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PROSKAUER ROSE LLP One International Place Boston, MA 02110			EXAMINER BERMAN, SUSAN W	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/696,709	<b>Applicant(s)</b> MERRILL ET AL.
	<b>Examiner</b> /Susan W. Berman/	<b>Art Unit</b> 1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 January 2010.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 124-140 is/are pending in the application.

4a) Of the above claim(s) 128-134 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 124-127 and 135-140 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/06)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application (PTC-152)  
 6) Other: \_\_\_\_\_

***Response to Amendment***

See the rejection of claims 135-140 under 35 U.S.C. 112, first paragraph, herein below.

***Response to Arguments***

Applicant's arguments filed 01/13/2010 have been fully considered but they are not persuasive.

Shalaby et al: Applicant argues that Shalaby et al teach irradiation at a dose of 2.50 Mrads, which dose would be expected to generate free radicals and not quench free radicals. This argument is not persuasive because Shalaby et al teach that exposure to high energy radiation results in crosslinking and further that crosslinking is enhanced upon irradiation in an acetylene environment. The enhanced crosslinking would be expected to "quench" free radicals, as set forth in the instant claims. Shalaby et al teach that the crosslinked UHMWPE composites may be irradiation sterilized without decline in physical properties, thus teaching that free radicals have been quenched in the disclosed process (column 2, lines 45-58). Applicant's claims 124-127 recite "quenching residual free radicals" after irradiation but do not set forth any method steps to quench free radicals. Therefore, the instant claims are considered to read on chemical methods for quenching free radicals, such as the enhanced crosslinking upon irradiation in an acetylene environment taught by Shalaby et al (column 3, lines 9-18, and column 6, lines 1-10).

Applicant argues that the instant claims are to be interpreted in light of the specification, evidently to be limited to radiation doses higher than those taught by Shalaby et al. Applicant is reminded that the disclosure of "exposure to high energy radiation" taught by Shalaby et al is not limited to the 2.50 Mrads used in the Examples of Shalaby et al, just as applicant's claim

language is not limited to radiation doses other than 2.50 Mrads. Shalaby et al clearly teach that the high energy radiation employed crosslinks the UHMWPE compositions and unexpectedly enhances certain physical properties, therefor Shalaby et al do not simply teach sterilization irradiation, as argued by applicant (see column 6, lines 5-7). Applicant's claims 124-127 do not recite any specific kind of radiation or radiation dose to be applied to the UHMWPE to distinguish the instantly claimed method from the disclosure of 2.5 Mrads employed in the Examples of Shalaby et al. Applicant is invited to recite the irradiation dose suitable in the instantly claimed invention in the instant claims in order to distinguish the instantly claimed method from that taught in the prior art. Applicant argues differences between the disclosure of Shalaby et al and the instantly claimed method that are not persuasive of patentability because the features argued are not set forth in the instant claims.

Applicant argues that the composite disclosed by Shalaby et al is not the same as the preform set forth in the instant claims. Applicant argues that Shalaby et al do not teach pre-heating the disclosed UHMWPE construct polymer-fiber. Applicant further argues that Shalaby et al teach melting UHMWPE powder in order to avoid melting the fibers of the composite product. In response, it is noted that Shalaby et al teach melting UHMWPE powder in contact with UMWPE fibers to obtain a reinforced composition by heating for a time necessary to melt the powder and then cooling the composite. Shalaby et al also teach heating sheets of polymeric matrix and reinforcement to a temperature and for a time to melt the film and coat the reinforcement so that a unitary solid is produced upon cooling. The composites, which have been heated prior to irradiation, are then irradiated. Applicant's claim language merely requires "pre-heating an ultrahigh molecular weight polyethylene (UHMWPE) preform at a temperature

greater than ambient temperature and less than the decomposition temperature of the UHMWPE for a period of time greater than 30 minutes". The composite disclosed by Shalaby et al is considered the equivalent of an UHMWPE preform because Shalaby et al teach that the composite is suitable for fabricating medical implants.

Applicant again alleges that Shalaby et al do not teach heating or melting to allow free radicals to recombine in the final product and that the final product will possess free radicals and be susceptible to oxidation. However, applicant has not provided any evidence to support this allegation. Applicant cites Shalaby et al column 4, lines 56-58, for support of the argument put forth. What Shalaby et al teach in column 4, lines 56-62, is to preferably process UHMWPE in an inert environment to avoid "transient crosslinking" formed in the presence of oxygen. This disclosure teaches a method for avoiding accelerated oxidation at elevated temperatures, not that the disclosed method results in presence of free radicals and susceptibility to oxidation. It is further noted that applicant's claims are drawn to a method not to the product produced.

Sun et al: Applicant argues that Sun et al do not disclose quenching free radicals formed upon irradiation. This argument is not persuasive for the following reasons. It is noted that the claim recitation "and quenching residual free radicals...preform" does not limit the manner of quenching free radicals. Sun et al specifically teach quenching free radicals remaining after irradiation by heat treatment followed by cooling (column 6, lines 48-51, and column 8, lines 11-20). No evidence to the contrary has been made of record. Applicant's claim language does not set forth any specific steps for quenching free radicals that distinguish the instantly claimed method from that taught by Sun et al.

Double Patenting Rejections: The double patenting rejections of record are maintained.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 124-127 and 135-140 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is reminded that claim language should correspond to the description of the invention as originally filed.

With respect to claims 124-127, while applicant teaches pre-heating, the examiner has not found any disclosure of pre-heating “at a temperature greater than ambient temperature and less than the decomposition temperature” or “for a period of time greater than about 30 minutes”. What applicant discloses in the MIR method is heating above the melting temperature of UHMWPE for a time period “for about 30 minutes to about 2 hours” before irradiation and cooled to about 25<sup>0</sup>C after irradiation (pages 29-31). Alternatively, applicant discloses “pre-heating to a temperature below the melting temperature of the UHMWPE”, irradiation of the UHMWPE, followed by heating to a temperature above the melting temperature for a time period of about 0.5 minutes to about 24 hours, preferably about 1 hour to about 3 hours and most preferably for 2 hours so there are no detectable free radicals in the CIR or WIR method (pages 21-24). The examiner has not found any disclosure to support the instant claim recitation

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“quenching residual free radicals” after pre-heating and irradiation. What applicant discloses is a cooling step after irradiation and that the disclosed method provides “crosslinked UHMWPE having substantially no detectable free radicals”. The method disclosed for obtaining “crosslinked UHMWPE having substantially no detectable free radicals” requires heating the irradiated UHMWPE after irradiation to above the melting temperature of UHMWPE (pages 14, 20 and 21).

With respect to claim 125, the examiner has not found any disclosure of the recited cooling after the quenching step “to a temperature below the melting temperature of the polyethylene”. What is disclosed is cooling to room temperature after the step of heating irradiated UHMWPE to above the melting temperature to provide “substantially no detectable free radicals”. See pages 18,

With respect to claims 135-137, a step for obtaining “substantially no free radicals” disclosed in the specification on pages 14 and 21-22, wherein methods including the instantly claimed pre-heating are disclosed, i.e. “CIR” and “WIR” methods, requires heating the irradiated UHMWPE above the melting temperature of the UHMWPE. No disclosure has been found of the recited heating the irradiated UHMWPE preform to a temperature “above ambient temperature” to “quench” free radicals or of a “quenching step”. What is disclosed in the instant specification is a method wherein, subsequent to irradiation, the irradiated UHMWPE is heated above the melting temperature to provide a product having substantially no free radicals. The method disclosed should be clearly set forth in the instant claims.

With respect to claims 138-140, the disclosure in the specification is that the UHMWPE preform is irradiated at a dose of “about 4 Mrads to about 30 Mrads”, not at a dose of “about 4.0 Mrads to about 30 Mrads” as set forth in the claims. See page 19 of the sepcificaiton.

Claims 124-127 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Heating irradiated UHMWPE above the melting temperature of the UHMWPE during the quenching of residual free radicals step discloses as being critical or essential to the practice of the invention, is not included in the claim(s). Therefor the claims, as written, are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The disclosure of “quenching residual free radicals” after pre-heating and irradiation in the instant specification requires heating above the melting temperature of UHMWPE.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 124-127 are rejected under 35 U.S.C. 102(e) as being anticipated by Shalaby et al (5,824,411). Shalaby et al disclose a method that comprises melting an UHMWPE “construct

polymer-fiber" and irradiating the resulting composite with high energy radiation to sterilize and crosslink the composites of UHMWPE. See column 2, lines 11-27, column 3, lines 9-18, column 5, line 32, to column 6, line 10, and Examples 1 and 5. Shalaby et al disclose heating sheets of polymeric matrix and reinforcement to a temperature and for a time to melt the film and coat the reinforcement so that a unitary solid composite, i.e. a preform, is produced under pressure by heating and then cooling. The composite is then treated with high energy radiation in the presence of acetylene in order to sterilize and crosslink the composite UHMWPE. Radiation causes free radicals to form that are then "quenched" by the disclosed crosslinking step in the presence of acetylene.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 124-127 and 135-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al (5,414,049). Sun et al teach a method for forming a medical implant comprising annealing a medical implant and then radiation sterilizing the implant (column 5, lines 38-67, and column 6, lines 42-43). The irradiated implant is then further annealed to reduce free radicals (column 6, lines 48-51). The difference from the instantly claimed process is that Sun et al teach treating a formed implant rather than a preform. It would have been obvious to one skilled in the art at the time of the invention to apply the process steps taught by Sun et al to a polyethylene

preform. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of imparting the desirable properties taught by Sun et al to a preform material since the polymeric material is polyethylene in the implant and in the preform.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-127 and 135-140 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-126 and 128-134 of copending Application No. 10/948440. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. irradiating and heating a polyethylene article, are set forth in the claims of '440 and in the instant claims. The instantly claimed step of heating to a temperature less than the decomposition temperature is considered to encompass the melting step set forth in the claims of '440. Alternatively, the melting step set forth in the claims of '440 corresponds to the step of quenching free radicals set forth in the instant claims and the comprising language of the claims

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of '440 encompasses the pre-annealing step in the instant claims. With respect to claims 138-140, claim 134 of Application '440 recites irradiation with a dose from about 5 to about 100 Mrad, thus encompassing the instantly claimed 4 to 30 Mrads. With respect to claims 126 and 127, It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '440.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 and 135-140 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124, 126-129 and 135-137 of copending Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the polyethylene, are set forth in the claims of '209 and in the instant claims. With respect to claims 126-127, It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '209. With respect to claims 135-137, the comprising language of the claims of application '209 encompasses a step of quenching free radicals after irradiation. With respect to claims 138-140, the claims of Application '209 recite a radiation dose greater than 1 Mrad and a greater than 20 Mrad.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claims 124-127 and 135-140 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-129 of copending Application No. 10/696362. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the UHMWPE are set forth in the claims of '362 and in the instant claims. The step of heating above the melting temperature set forth in the claims of '362 is encompassed by the step of pre-annealing at a temperature less than the decomposition temperature of polyethylene set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 and 135-140 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 114 and 124-129 of copending Application No. 10/901089. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the heated UHMWPE are set forth in the claims of '089 and in the instant claims. The step of heating above the melting temperature set forth in the claims of '089 is encompassed by the step of pre-annealing at a temperature less than the decomposition temperature of polyethylene set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

Shen et al (6,228,900, having an effective filing date of 07-09-1996). Shen et al disclose a method comprising irradiation of an UHMWPE preform with from 1 to 100 Mrad and annealing or remelting the irradiated UHMWPE. Shen et al do not mention pre-heating the UHMWPE preform before irradiating the preform. However, applicant's claims do not clearly set forth the sequence in which the recited "pre-heating" and "irradiating" and "quenching" take place, or whether the irradiating is performed on the preform while heated or after pre-heating and cooling to room temperature, for example.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB  
4/12/2010

/Susan W Berman/  
Primary Examiner  
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